UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/735,461 | 12/11/2003 | Michael P. Czech | UMY-055 | 3119 |

959 7590 07/01/2005

LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

| EXAMINER | |
|---|---|
| ASHEN, JON BENJAMIN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1635 | |

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/735,461 | CZECH ET AL. | |
| | Examiner | Art Unit | |
| | Jon B. Ashen | 1635 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-26, drawn to methods of inhibiting the expression or activity of Akt1, Akt2, CISK or Myo1c in a cell or an adipocyte comprising introducing an siRNA a cell or an adipocyte, classified in class 514, subclass 44.

II. Claim 27, drawn to a method of identifying a gene that affects glucose transport comprising introducing into an adipocyte an siRNA targeted against a gene and assaying the reduction of glucose transport in the cell, classifiable in class 424, subclass 9.2.

III. Claims 28 and 30-31, drawn to a method of identifying an insulin response modulator comprising contacting a cell expressing a protein identified by the method of Invention II with a test compound and determining the ability of the test compound to modulate an activity of the protein identified by the method of Invention II, classifiable in class 424, subclass 9.2.

IV. Claims 29-31, drawn to a method of identifying an insulin response modulator comprising contacting a cell expressing a protein identified by the method of Invention II with a test compound and determining the ability

of the test compound to modulate expression of the protein identified by the method of Invention II, classifiable in class 424, subclass 9.2.

V. Claims 32 and 33, drawn to an insulin response modulator and a pharmaceutical composition thereof as identified by the method of Invention III, that modulates an activity of the protein identified by the method of Invention II, classifiable in class 514, subclass 1.

VI. Claims 32 and 33, drawn to an insulin response modulator and a pharmaceutical composition thereof as identified by the method of Invention IV, that modulates expression of the protein identified by the method of Invention II, classifiable in class 514, subclass 1.

VII. Claims 34-37, drawn to a method of treatment comprising administering an insulin response modulator of Invention V as identified by the method of Invention III, that modulates an activity of the protein identified by the method of Invention II, classifiable in class 514, subclass 2.

VIII. Claims 34-37, drawn to a method of treatment comprising administering an insulin response modulator of Invention VI as identified by the method of Invention IV, that modulates expression of the protein identified by the method of Invention II, classifiable in class 514, subclass 44.

2. The inventions are distinct, each from the other because of the following reasons:

3. The Inventions encompassed in group I, and Inventions II-VIII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

The inventions encompassed by group I are drawn to methods of inhibiting the expression or activity of Akt1, Akt2, CISK or Myo1c in a cell or an adipocyte comprising introducing an siRNA into a cell or an adipocyte. Invention II is drawn to a method of identifying a gene that affects glucose transport comprising introducing into an adipocyte an siRNA targeted against a gene and assaying the reduction of glucose transport in the cell wherein the gene that is targeted is unspecified. Invention III is drawn to a method of identifying an insulin response modulator comprising contacting a cell expressing a protein identified by the method of Invention II with a test compound and determining the ability of the test compound to modulate an activity of the protein identified by the method of Invention II. Invention IV is drawn to a method of identifying an insulin response modulator comprising contacting a cell expressing a protein identified by the method of Invention II with a test compound and determining the ability of the test compound to modulate expression of the protein identified by the method of Invention II. Invention V is drawn to an insulin response modulator and a pharmaceutical composition thereof as identified by the method of Invention III, that modulates an activity of the protein identified by the method of Invention II. Invention VI

is drawn to an insulin response modulator and a pharmaceutical composition thereof as identified by the method of Invention IV, that modulates expression of the protein identified by the method of Invention II. Invention VII is drawn to a method of treatment comprising administering an insulin response modulator of group V as identified by the method of Invention III, that modulates an activity of the protein identified by the method of Invention II. Invention VIII is drawn to a method of treatment comprising administering an insulin response modulator of Invention VI as identified by the method of Invention IV, that modulates expression of the protein identified by the method of Invention II.

In the instant case the different inventions are not disclosed as capable of use together and have different functions. The inventions encompassed by group I each function to provide a method of inhibiting the expression or activity of Akt1, Akt2, CISK or Myo1c respectively, in a cell or an adipocyte, by introducing an siRNA targeted to Akt1, Akt2, CISK or Myo1c respectively, into a cell or an adipocyte. Invention II functions to provide a method of identifying a gene that effects glucose transport. Invention III functions to provide a method of identifying a compound that modulates an activity of a protein that effects glucose transport. Invention IV functions to provide a method of identifying a compound that modulates the expression of a protein that effects glucose transport. Invention V is a yet to be identified compound that can function as an antibody to modulate the activity of a protein that effects glucose transport. Invention VI is a yet to be identified compound that can function as a ribozyme to modulate the expression of protein that effects glucose transport. Invention

VII functions to provide a method of treatment by administering a compound that modulates an activity of a protein that effects glucose transport. Invention VII functions to provide a method of treatment by administering a compound that modulates the expression of a protein that effects glucose transport.

Furthermore, searching any of the Inventions encompassed in group I or Inventions II-VIII together, would impose a serious and undue search burden. In the instant case, prior art searches of the instantly claimed methods and compositions would not be coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases. In regards to the Inventions encompassed in group I, these searches would have to include nucleotide sequence searches. Search of each of these inventions would also require, at least, searches of distinct method steps required for methods of treatment or for methods of identifying compounds, that would not be required by the other methods or the compositions. These searches would then require subsequent in-depth analysis of all relevant prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of any of the Inventions encompassed in group I or Inventions II-VIII together.

4. Group I is further restricted as follows:

5. Group I comprises claims to the following patentably distinct inventions: Methods of inhibiting the expression or activity of a) Akt1 (SEQ ID NO: 5 or SEQ ID NO: 6), b)

Akt2 (SEQ ID NO: 7 or SEQ ID NO: 8), c) CISK or d) Myo1c (SEQ ID NO: 13 of 14) in a cell or an adipocyte comprising introducing an siRNA into cell or an adipocyte wherein the siRNA targets SEQ ID NO: 5, 6, 7, 8, 13 or 14 (as above).

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the instantly claimed genes listed in claims 7-9 (Atk1, Atk2, CISK and Myo1c) and the instantly claimed siRNA sequences that target SEQ ID NO: 5, 6, 7, 8, 13 or 14 (as listed in claims 10, 12, 13, 15, 16 and 18) are subject to restriction.

The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434)

Claims 7-9 specifically claim siRNAs targeted to Akt1 or Akt2, CISK or myo1c respectively. Claims 10 and 12, 13 and 15 and 16 and 18 specifically claim siRNAs that target Akt1, (SEQ ID NO:5 or 6), Akt2 (SEQ ID NO: 7 or 8) or myo1c (SEQ ID NO: 13 or 14) respectively. In the instant case, the claimed siRNA sequences that each target different genes (claims 7-9) or specified regions of said different genes (claims 10, 12, 13, 15, 16, and 18) and modulate expression of these different genes, are considered to be unrelated, since each siRNA sequence claimed is structurally and functionally independent and distinct for the following reasons: each siRNA sequence has a unique nucleotide sequence, each siRNA sequence targets a different and specific region of an Akt1, Akt2, CISK or myo1c nucleic acid, and absent evidence to the contrary, each siRNA, upon binding to its target, is expected to functionally modulate (increase or

decrease) the expression that target to varying degrees. As such the siRNA sequences in claims 7-10, 12, 13, 15, 16 and 18 are not considered to constitute a proper genus, and are therefore subject to restriction.

Furthermore, a search of more than one (1) of the siRNA target sequences claimed in claims 7-10, 12, 13, 15, 16 and 18 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed siRNA sequences. MPEP 808.02 states in part: Where the related inventions as claimed are shown to be distinct under the criteria of MPEP 806.05(C) - 806.05(i), the examiner, in order to establish reasons for insisting upon restriction, must show, by appropriate explanation, one of the following:

(C) A different field of search: Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together.

It is noted that a search of the available sequence databases produces a listing of references disclosing the sequence most similar to the query sequence. This is the "place" where the examiner searches for prior art. The prior art relating to another query sequence will not be found in this "place"- a different listing of references must be generated and searched by the examiner. Thus a different search is shown, and restriction is proper.

It is also noted herein that "up to 10" includes one (1) and that, in view of the foregoing, one (1) siRNA sequence is considered to be a reasonable number of

sequences for examination. Accordingly, applicant is required to elect one (1) method that employs siRNA to target a single target gene as set forth in claims 7-9. If Applicant elects the Atk1, Atk2 or myo1c target gene, Applicant is required to elect a single siRNA target sequence from claims 12, 13, 15, 16 and 18, that corresponds with the elected target gene. The claims of group I will be examined in their full scope insofar as they read on the elected subject matter (the elected target gene and/or the elected SEQ ID NO: ). Note that this is not a species election.

6. This application contains claims directed to the following patentably distinct species of the claimed invention: Claims 30 drawn to positive modulators identified by the method of claim 28 or 29 and claim 31 drawn to negative modulators identified by the method of claim 28 or 29.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 28 and 29 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Claim 36 is generic to a plurality of disclosed patentably distinct species comprising Type II diabetes, insulin resistance and obesity. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file

folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba

93 TC 1600